

IFW

PATENT

Attorney Docket No.: 34545/US/4/RFT/SKS

Attorney File No.: 459258-00039

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BARRETT et al.

Serial No. 10/816,551

Filing Date: March 31, 2004

For: *Treating or Preventing Hot Flashes
Using Prodrugs of GABA Analogs*

Examiner: Not Assigned

Art Unit: 1614

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

Dated: April 1, 2005

Signed: [Signature]

Luke Szymanski

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1287 Off. Gaz. Pat. Office 163, 10/19/2004, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

None of the foregoing references are believed to disclose the invention as claimed.

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.

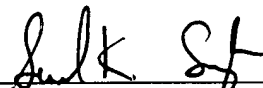
Serial No. 10/816,551
Filing Date: March 31, 2004

Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. While no additional fee is believed to be due, if this belief is in error the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 459258-00039 [34545/US/4/RFT/SKS]).

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: 4/1/05
Customer Number: 32940
Dorsey & Whitney LLP
Intellectual Property Department
Four Embarcadero Center, Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989
Facsimile: (415) 398-3249

By: 
Sunil K. Singh, Reg. No. 45,298

Attachments : Form PTO/SB/8A, Substitute for form 1449
57 Cited References
Return Postcard



Substitute for form 1449A/PTO (Modified)				Complete if Known	
				Application Number	10/816,551
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	March 31, 2004
				First Named Inventor	Barrett, Ronald W.
				Art Unit	1614
				Examiner Name	Not Assigned
(use as many sheets as necessary)				Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)
Sheet	1	of	4		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	2,996,431	08-15-1961	Barry	
	A2	3,139,383	06-30-1964	Neville	
	A3	3,402,240	09-17-1968	Cain et al.	
	A4	3,811,444	05-21-1974	Heller et al.	
	A5	3,845,770	11-05-1974	Theeuwes et al.	
	A6	3,916,899	11-04-1975	Theeuwes et al.	
	A7	3,962,414	06-08-1976	Michaels	
	A8	3,992,518	11-16-1976	Chien et al.	
	A9	4,024,175	05-17-1977	Satzinger et al.	
	A10	4,066,747	01-03-1978	Capozza	
	A11	4,070,347	01-24-1978	Schmitt	
	A12	4,079,038	03-14-1978	Choi et al.	
	A13	4,083,949	04-11-1978	Bendikt	
	A14	4,093,709	06-06-1978	Choi et al.	
	A15	4,200,098	04-29-1980	Ayer et al.	
	A16	4,285,987	08-25-1981	Ayer et al.	
	A17	4,421,736	12-20-1983	Walters	
	A18	4,434,153	02-28-1984	Urguahart et al.	
	A19	4,721,613	01-26-1988	Urguahart et al.	
	A20	4,752,470	06-21-1988	Mehta	
	A21	4,816,263	03-28-1989	Ayer et al.	
	A22	4,820,523	04-11-1989	Shtohryn et al.	
	A23	4,853,229	08-01-1989	Theeuwes et al.	
	A24	5,563,175	10-08-1996	Silverman et al.	
	A25	5,698,155	12-16-1997	Grosswald et al.	
	A26	5,707,663	01-13-1998	Ayer et al.	
	A27	6,020,370	02-01-2000	Horwell et al.	
	A28	6,024,977	02-15-2000	Yatvin et al.	
	A29	6,103,932	08-15-2000	Silverman et al.	
	A30	6,117,906	09-12-2000	Silverman et al.	
	A31	6,171,615	01-09-2001	Roussin et al.	
	A32	6,310,098	10-30-2001	Guttuso, Jr.	
	A33	6,375,987	04-23-2002	Farah et al.	
	A34	6,379,700	04-30-2002	Joachim et al.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and selection option 2

Substitute for form 1449A/PTO (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/816,551
				Filing Date	March 31, 2004
				First Named Inventor	Barrett, Ronald W.
				Art Unit	1614
				Examiner Name	Not Assigned
Sheet	2	of	4	Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A35	US App. No. 10/313,825		Bhat et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code ² Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1	GB 2,362,646	11-28-2001	Bryans et. al.		
	B2	EP 1,178,034 A1	02-06-2002	Bryans et. al.		
	B3	EP 1,201,240 A2	05-02-2002	Bryans et. al.		
	B4	WO 92/09560 A1	06-11-1992	Silverman		
	B5	WO 93/23383 A1	11-25-1993	Silverman et al.		
	B6	WO 97/29101 A1	08-14-1997	Horwell et al.		
	B7	WO 97/33858 A1	09-18-1997	Horwell et al.		
	B8	WO 97/33859 A1	09-18-1997	Horwell et al.		
	B9	WO 98/17627 A1	04-30-1998	Bryans et al.		
	B10	WO 99/08671 A1	02-25-1999	Guglietta et al.		
	B11	WO 99/21824 A1	05-06-1999	Bryans et al.		
	B12	WO 99/31057 A1	06-24-1999	Bryans et al.		
	B13	WO 99/31075 A1	06-24-1999	Bryans et al.		
	B14	WO 99/61424 A1	12-02-1999	Bryans et al.		
	B15	WO 00/15611 A1	03-23-2000	Bryans et al.		
	B16	WO 00/31020 A1	06-02-2000	Bellioti et al.		
	B17	WO 00/50027 A1	08-31-2000	Bryans et al.		
	B18	WO 01/90052 A1	11-29-2001	Bryans et al.		
	B19	WO 02/00209 A2/A3	01-03-2002	Bryans et al.		
	B20	WO 02/100347 A2	12-19-2002	Gallop et al.		
	B21	WO 02/100349 A2/A3	12-19-2002	Gallop et al.		
	B22	WO 02/28881 A1	04-11-2002	Gallop et al.		
	B23	WO 02/28411 A1	04-11-2002	Gallop et al.		
	B24	WO 02/28883 A1	04-11-2002	Gallop et al.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and selection option 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/816,551
				Filing Date	March 31, 2004
				First Named Inventor	Barrett, Ronald W.
				Group Art Unit	1614
				Examiner Name	Not Assigned
Sheet	3	of	4	Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code ² Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B25	WO 02/32376 A2	04-25-2002	Gallop et al.		
	B26	WO 02/42414 A2/A3	05-30-2002	Gallop et al.		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ⁶
	C1	ALDERMAN, "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. & Prod. Mfr.</i> 1984, 5(3) 1-9.				
	C2	BAMBA et al., "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> 1979, 2, 307.				
	C3	BRYANS et al., "3-Substituted GABA Analogs with Central Nervous System Activity: A Review," <i>Med. Res. Rev.</i> 1999, 19, 149-177.				
	C4	BRYANS et al., "Identification of Novel Ligands for the Gabapentin Binding Site on the $\alpha_2\delta$ Subunit of a Calcium Channel and Their Evaluation as Anticonvulsant Agents," <i>J. Med. Chem.</i> 1998, 41, 1838-1845.				
	C5	COLEMAN et al., "Polymer Review: A Practical Guide to Polymer Miscibility," <i>Polymers</i> 1990, 31, 1187-1231.				
	C6	DURING et al., "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," 1989, <i>Ann. Neurol.</i> 25:351.				
	C7	FINCHER, "Particle Size of Drugs and Its Relationship to Absorption and Activity," <i>J. Pharm. Sci.</i> 1968, 57, 1825-1835.				
	C8	GEE et al., "The Novel Anticonvulsant Drug, Gabapentin (Neurontin), Binds to the $\alpha_2\delta$ Subunit of a Calcium Channel," <i>J. Biol. Chem.</i> 1996, 271, 5768-5776.				
	C9	GOLDBERG et al., "Transdermal Clonidine for Ameliorating Tamoxifen-Induced Hot Flashes," <i>J. Clin. Onc.</i> 1994, 12, 155-158.				
	C10	GOODSON, "Medical Applications of Controlled Release," <i>supra</i> , vol., 2, pp. 115-138 (1984).				
	C11	GUTTUSO et al., "Gabapentin's Effects on Hot Flashes in Postmenopausal Women: A Randomized Controlled Trial," <i>Obstet. Gynecol.</i> 2003, 101, 337-345.				
	C12	GUTTUSO, "Gabapentin's Effects on Hot Flashes an Hypothermia," <i>Neurology</i> 2000, 54, 2161-2163.				
	C13	HOES et al., "The Application of Drug-Polymer Conjugates in Chemotherapy," <i>Drug Carrier Systems</i> 1989, 9, 57-10				
	C14	JEFFERY et al., "Gabapentin for Hot Flashes in Prostate Cancer," <i>Ann. Pharmacother.</i> 2002, 36, 433-435.				
	C15	JEZYK et al., "Transpot of Pregabalin in Rat Intestine and Caco-2 Monolayers," <i>Pharm. Res.</i> 1999, 16, 519-526.				
	C16	KOURIEFS et al., "Hot Flashes and Prostate Cancer: pathogenesis and treatment," <i>British J. Urol. Int.</i> 2002, 89, 379-383.				
	C17	KRONENBERG et al. "Thermoregulatory physiology of menopausal hot flashes: a review," <i>Can. J. Physiol. Pharmacol.</i> 1987, 65, 1312-1324.				
Examiner Signature				Date Considered		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/816,551	
			Filing Date	March 31, 2004	
			First Named Inventor	Barrett, Ronald W.	
			Group Art Unit	1614	
			Examiner Name	Not Assigned	
Sheet	4	of	4	Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C18	LANGER <i>et al.</i> , "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J Macromol. Sci. Rev. Macromol Chem.</i> 1983, 23:61.	
	C19	LANGER, "New Methods of Drug Delivery," 1990, <i>Science</i> 249:1527-1533.	
	C20	LEONG <i>et al.</i> , "Polymeric Controlled Drug Delivery," <i>Adv. Drug Delivery Rev.</i> 1987, 1, 199-233.	
	C21	LEVY <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> 1985 228: 190-192.	
	C22	LOPRINZI <i>et al.</i> , "Megestrol Acetate for the Prevention of hot Flashes," <i>N. Engl. J. Med.</i> 1994, 331, 347-351.	
	C23	LOPRINZI <i>et al.</i> , "Pilot Evaluation of Gabapentin for Treating Hot Flashes," <i>Mayo Clin. Proc.</i> 2002, 77, 1159-1163.	
	C24	LOPRINZI <i>et al.</i> , "Venlafaxine in management of hot flashes in survivors of breast cancer; a randomized controlled trial," <i>Lancet</i> 2000, 356, 2059-2063.	
	C25	LU, "Dimensionless Presentation for Drug Release From a Coated Pure Drug Bead: 2 Experiment," <i>Int. J. Pharm.</i> , 1994, 112, 117-124.	
	C26	MAGNUS, "Nonepileptic Uses of Gabapentin," <i>Epilepsia</i> , (40) (Suppl. 6): S66-S72 (1999).	
	C27	QUELLA <i>et al.</i> , "Pilot Evaluation of Venlafaxine for the Treatment of Hot Flashes in Men Undergoing Androgen Ablation Therapy for Prostate Cancer," <i>J. Urol.</i> 1999, 162, 98-102.	
	C28	SAUDEK <i>et al.</i> , "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 1989, 321: 574.	
	C29	SEFTON, "Implantable Pumps," <i>CRC Crit Ref Biomed. Eng.</i> 14:201, 1987	
	C30	SHANAFELT <i>et al.</i> , "Pathophysiology and Treatment of Hot Flashes," <i>Mayo Clin. Proc.</i> 2002, 77, 1207-1218.	
	C31	VERMA <i>et al.</i> , "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 2000, 26:695-708.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.